E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0479; FRL-11131-01-OCSPP]

Indaziflam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indaziflam in or on multiple commodities discussed later in this document. Bayer CropScience has requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections and requests for hearings must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0479, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-

1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0479 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Addresses for mail and hand delivery of objections and hearing

requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0479, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the ***Federal Register*** of July 20, 2022 (87 FR 43231) (FRL-9410-03-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F9002) from Bayer CropScience, 800 N. Lindbergh Blvd., St. Louis, MO, 63141. The petition requested that 40 CFR 180.653 be amended by revising tolerances for residues of indaziflam *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the following raw agricultural commodities: Grass Forage, Fodder, and Hay Group 17, forage at 50 parts per million (ppm); Grass Forage, Fodder, and Hay Group 17, hay at 80 ppm; and livestock

fat, meat, meat byproducts, milk and milk, fat at 0.1, 0.01, 0.3, 0.015, and 0.4 ppm respectively. (The notice of filing published on July 20, 2022, incorrectly identified the tolerance levels for meat byproducts as 0.30 ppm and for milk, fat as 0.04 ppm, rather than 0.3 ppm and 0.4 ppm as the petition requested.) That document referenced a summary of the petition, which is available in the docket, https://www.regulations.gov. No comments were received in response to the July 20, 2022, notice of filing.

EPA is establishing one tolerance at a different level than requested by the petitioner. The reason for this change is explained in Unit IV.C. In addition, EPA is not revising the established tolerances for meat (i.e., Cattle, meat; Goat, meat; Horse, meat; and Sheep, meat) because the revised anticipated residues remain lower than the current tolerance level (0.01 ppm).

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indaziflam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indaziflam follows.

In an effort to streamline its publications in the ***Federal Register***, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for indaziflam in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to indaziflam and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of indaziflam, see Unit III.A. of the indaziflam tolerance rulemaking published in the ***Federal Register*** of October 10, 2019 (84 FR 54510) (FRL-9999-70).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for indaziflam used for human health risk assessment, please reference Unit III.B. of the October 10, 2019, rulemaking.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the proposed removal of the grass forage grazing restriction and the grass hay cutting restriction from certain indaziflam product labels, resulting in increased associated residues on animal commodities. The acute and chronic (food and drinking water) dietary exposure assessments in support of the proposed label amendments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined acute and chronic dietary

exposure assessments assumed 100 percent crop treated (PCT), tolerance-level residues for all crops, and maximum anticipated residues to address all residues of concern in ruminant commodities.

Drinking water and non-occupational exposures. The drinking water numbers have not changed as a result of the proposed removal of the grass forage grazing restriction and the grass hay cutting restriction. For a detailed summary of the drinking water analysis for indaziflam used for the human health risk assessment, please reference Unit III.C.2. of the October 10, 2019, rulemaking.

Indaziflam is currently registered for the following uses that could result in residential exposures: turf, gardens, and trees. While there are no proposed residential uses in the current action, EPA's residential (non-occupational) exposure and risk assessment has been revised since the October 10, 2019, rulemaking. The following exposure estimates are used in the aggregate assessment for indaziflam because they are the most conservative of the residential handler and post-application scenarios. The residential exposure for children 1 to <2 years old is combined dermal and incidental oral (hand-to-mouth) exposure to turf (i.e., recreational premises/areas) applications via high contact lawn activities. The residential exposure for children 6 to <11 years old is dermal exposure to turf applications via golfing activities and for adults is combined dermal and inhalation exposure from handling indaziflam via ready-to-use (RTU) trigger spray bottle applications. None of the residential exposures are of concern.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to indaziflam and any other substances and indaziflam does not appear to produce a toxic metabolite produced by other substances. For the purposes of

this action, therefore, EPA has not assumed that indaziflam has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the October 10, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD; they are 21% for all infants (<1 year old), the subgroup with the highest exposure. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD; they are 15% of the cPAD for the children 1 to 2 years old, the group with the highest exposure.

EPA aggregated short-term exposure to indaziflam based on the residential and dietary routes of exposure. The short-term aggregate MOEs were 360 for adults; 5,100 for children 6 to <11 years old; and 540 for children 1 to <2 years old. These values do not exceed the level of concern, which is an MOE below 100, so the risk estimates are not of concern. Acute and chronic aggregate risks are equivalent to the acute and chronic dietary risks and are not of concern. Indaziflam is not registered for any use patterns that would result in intermediate-term residential exposure, so intermediate-term aggregate risk is the same as the chronic dietary risk and is not of concern.

Based on the lack of evidence of carcinogenicity or genotoxicity, indaziflam is classified

as “not likely to be carcinogenic to humans”. Therefore, EPA does not expect indaziflam to pose a cancer risk from aggregate exposure.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to indaziflam residues. More detailed information on this action can be found in the document titled “Indaziflam. Human Health Risk Assessment for the Removal of Forage Grazing and Hay Cutting Intervals for Pastures, Rangeland, Natural Areas, and Grazed Non-Crop Areas, and the Increased Application Rate to Rights-of-Way” in docket ID EPA-HQ-OPP-2022-0479.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the indaziflam tolerance rulemaking published in the ***Federal Register*** of June 24, 2020 (85 FR 37760) (FRL-10008-92).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex Alimentarius has not established any Maximum Residue Limits (MRLs) for indaziflam.

C. Revisions to Petitioned-For Tolerances

EPA is amending the tolerance for residues of indaziflam in or on Grass, forage, fodder and hay, group 17, forage to 40 ppm rather than at 50 ppm as proposed by the petitioner. Both EPA and the petitioner entered the proportioned grass forage residue data into the Organization

for Economic Development and Cooperation (OECD) tolerance calculator. The difference between the proposed and recommended tolerance values is likely due to a difference in rounding.

V. Conclusion

Therefore, the established tolerances for residues of indaziflam in or on the following commodities are revised to these levels: Cattle, fat at 0.1 ppm; Cattle, meat byproducts at 0.3 ppm; Goat, fat at 0.1 ppm; Goat, meat byproducts at 0.3 ppm; Grass, forage, fodder and hay, group 17, forage at 40 ppm; Grass, forage, fodder and hay, group 17, hay at 80 ppm; Horse, fat at 0.1 ppm; Horse, meat byproducts at 0.3 ppm; Milk at 0.015 ppm; Milk, fat at 0.4 ppm; Sheep, fat at 0.1 ppm; and Sheep, meat byproducts at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.),

do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the ***Federal Register***. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 17, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.653:

a. Amend table 1 to paragraph (a)(1) by revising the entries for "Grass, forage, fodder and hay, group 17, forage" and "Grass, forage, fodder and hay, group 17, hay".

b. Revise table 2 to paragraph (a)(2).

The revisions read as follows:

§ 180.653 Indaziflam; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Grass, forage, fodder and hay, group 17, forage	40
Grass, forage, fodder and hay, group 17, hay	80
* * * * * * *	

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(2) * * *

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.01
Cattle, meat byproducts	0.3
Goat, fat	0.1
Goat, meat	0.01
Goat, meat byproducts	0.3
Horse, fat	0.1

Horse, meat	0.01
Horse, meat by-products	0.3
Milk	0.015
Milk, fat	0.4
Sheep, fat	0.1
Sheep, meat	0.01
Sheep, meat by-products	0.3

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[FR Doc. 2023-15646 Filed: 7/24/2023 8:45 am; Publication Date: 7/25/2023]